

use liposomes with optimal pharmacological properties (enhanced tumor targeting) as carriers for their i.v. administration (12). As a result of these efforts, Annamycin was selected as the leading compound with these characteristics. We have previously reported that liposomal Annamycin is not cross-resistant with Dox in vitro and in vivo and is less cardiotoxic (13,14).

Lyophilization of preformed liposomes or of the liposome constituents followed on the day of use by reconstitution with an aqueous solution to obtain the liposome suspension has been successfully explored by us and others in the past (15, 16). Potential problems with formulations using preliposomal lyophilized powders are basically related to difficulties encountered with the reconstitution step to obtain a reproducible liposomal suspension. In this patent, we describe a modified lyophilization method for the preparation of a highly stable, easy to reconstitute, submicron liposome suspension of the lipophilic anthracycline Annamycin and we report on the crucial role played by a small amount of the surfactant Tween 20 in improving the characteristics of the formulation.

The present invention in one aspect concerns a pharmaceutical composition, comprising an anthracycline compound having the formula

